

LOCKABLE CONTAINER WITH INNER TRAY

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to co-pending U.S. Provisional application 60/520,143, filed on November 13, 2003. The entire disclosure of that prior filed application is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] This invention relates to a package that houses portable items on a tray configured to be inserted into an outer sleeve. This package may have one or more internal or external locks that prevent the tray from being pulled out of the sleeve. This package provides a child-resistant, senior-friendly package that can be opened and closed numerous times to access the items held by the tray.

BACKGROUND OF THE INVENTION

[0003] Conventional pharmaceutical packaging has shortcomings with regard to drug delivery devices, which create problems for both the manufacturer and end user. For example, it is known to distribute syringes, vials, inhalers, patches, test kits, or parts thereof in packaging that incorporates foam elements to separate and pad the product. Such conventional packaging normally holds the product in a vertical position; however, where conventional packaging holds the product in a horizontal position, the products are typically layered on top of each other. It is also known to distribute drug delivery devices loose – or loose, but individually wrapped – in conventional boxes without any means for holding or protecting the products.

[0004] The conventional manufacturer that incorporates foam or plastic elements in its packaging to protect the product carries an increased inventory and employs a more complicated manufacturing system to produce its packaging. Further, the conventional manufacturer typically produces one kind of package to be filled by automated means and another kind to be filled by hand, which also increases inventory and the number of product lines.

[0005] Conventional manufacturers of drug delivery device packaging typically do not provide a child-resistant feature to prevent unauthorized access, or a stopping feature to prevent

accidental spillage. Where these features do exist, they exist at the expense of easy access for the end user with limited dexterity. Neither does the known drug delivery device packaging provide ample space to place appropriately sized graphics, such as dose compliance instruction and warnings, for the end user with limited sight.

[0006] In addition, conventional manufacturers pack drug delivery devices tightly and in the most efficient manner possible – from the perspective of shipping cost savings – but, again, at the expense of the end user who has limited physical mobility, such as an end user with arthritis of the hands and fingers. Also conventional manufacturers are known to distribute only wholly-assembled drug delivery devices together, or parts of devices together, but not whole devices and parts together. For example, it is known to distribute syringes together or vials together on the same platform, but not syringes and vials together on the same platform.

[0007] End users are familiar with the disposal problems created by the use of drug delivery devices. Typically, spent patches, vials, needles, inhalers, syringes, barrels, and other devices or parts thereof should be sealed or otherwise protected in order to be disposed of safely. While it is known to dispose of syringes and needles in a separate device, such as a sealed plastic container, there remains a need for a drug delivery device packaging that also serves as a safe means of disposal.

[0008] It is apparent from a survey of the packaging arts that there exists a need for an apparatus that holds and protects all types of drug delivery devices and parts thereof, allows for improved manufacturing process, includes child-resistant and spill-prevention features, stores a variety of objects in response to the end users' needs, is fitted for easy access by the end user with limited dexterity, has sufficient area to receive graphics, and provides a means for safe disposal.

SUMMARY OF THE INVENTION

[0009] The present invention fulfills the needs identified above by providing packaging comprising an inner slide card/tray that is inserted within an outer sleeve. In some embodiments, the outer sleeve and inner slide card/tray both comprise elements configured to cooperatively engage the other to create a means for locking, means for releasing, and means for stopping.

[00010] In exemplary embodiments, the means for engaging include panels, tabs, catches, ribs, catches, abutments, edges, cutouts, apertures, and like elements, integral to or

attached to either the card or tray, configured to connect with similar elements associated with the outer sleeve, and referred to herein as the means for locking. The means for releasing include panels, tabs, ribs, abutments, edges, cutouts, catches, apertures, and like elements, integral to or attached to the outer sleeve, configured to uncouple engaged or locked elements. Thus, the present invention provides an optional child-resistant feature. A means for stopping comprise panels, tabs, ribs, catches, abutments, apertures, edges, cutouts, and like elements, integral to or attached to either the card or tray, configured to matingly engage similar elements associated with the outer sleeve. Thus, the present invention provides an optional spill-resistant feature to prevent the user from pulling the tray completely away from the outer sleeve.

[00011] Alternative embodiments include an apparatus and method for holding and storing drug delivery devices by providing an inner tray configuration that, by way of example and not limitation, protects a plunger from inadvertent activation; shields a needle from inadvertent exposure; allows easy access to a drug-filled container for removal and replacement; and collects and stores the spent devices. Accordingly, embodiments of the present invention provide an apparatus and system that is able to safely ship drug delivery devices for trans-epidermal, oral, or hypodermic administration, including pre-filled syringes, needles, vials, ampoules, protective shields, patches, inhalers, and parts thereof, and like devices, safely store the unused devices, and safely store the used devices until all can be safely disposed as unit.

[00012] Embodiments include a pre-formed tray attached to a paperboard card, and a monolithically formed card/tray combination. Compliance information or general information related to the medication or therapy may be positioned on or with the slide card, tray, or outer sleeve in a manner easily visible by the user. In one embodiment, indicia -- such as, but not limited to, time of day, days of the week, numerical sequence, or dosage amounts -- are positioned adjacent to the devices.

[00013] Another embodiment of the present invention comprises a slide card with an engaging tab and a tray receiving area. At least one pre-formed tray, configured to receive and hold at least one portable item, may be attached to the tray receiving area. An outer sleeve that receives the card and attached tray comprises a locking edge configured to engage the tab at a locking position. The outer sleeve also has an integral release configured to disengage the tab from the locking position. Yet another embodiment of the present invention includes a slide card constructed of one material, with a base panel and a tray receiving area located on the base panel. A pre-formed tray constructed of a different material, with at least one receiving recess, is attached to the card at the tray receiving area. Both may be fully inserted within a

void defined by an outer sleeve, through an open end of the sleeve. Another embodiment of the present invention is defined by a slide card and outer sleeve combination. Here the slide card comprises a means for engaging and at least one tray receiving area, together with a pre-formed tray configured to receive and hold at least one portable item, attached to the tray receiving area. Here the outer sleeve defines a void configured to receive the card and attached tray, and comprises a means for locking the card's means for engaging. The outer sleeve also includes an integral means for releasing configured to uncouple the means for engaging from the means for locking.

[00014] Other embodiments of the present invention include improved components, such as a monolithically fabricated tray with card. Here, a tray with card may be fabricated from any forming technique or process known to those skilled in the art, including but not limited to thermo-forming, vacuum forming, and injection molding. The tray with card includes an engaging panel hingedly attached to a second panel or the integral tray. The tray comprises at least one recess configured to receive and hold a portable item. A third panel, configured to fold over and cover the item(s) in the tray, may likewise be hingedly attached to either the second panel or tray. This improved component is configured to be inserted into an outer sleeve.

[00015] In practice, some embodiments of the present invention are configured to resist access to an item by securing the item in a lockable package. A method for resisting access to an item secured in an embodiment of the present invention comprises the following steps, presented in the following order for the purposes of teaching and not limitation. Provide a slide card with a means for engagement and a base panel. Attach a pre-formed tray comprising at least one receiving recess to the base panel and place an item in the recess. Provide an outer sleeve with an open end, an accessible void, and a means for locking the card. Align the card with the open end and orientate the means for engagement with the means for locking. Insert the card fully into the void to cause the means for engaging and means for locking to releaseably couple or connect.

[00016] Embodiments according to this invention offer at least the following advantages: lightness in weight, resistance to tampering, child-resistance, ease of access, excellent durability, ease of assembly, device protection, ease of storage, ease of disposal, the ability to present devices of different and unusual shapes, and excellent economy.

[00017] It is also contemplated that the present invention is not limited to pharmaceutical-related goods, but is applicable to a plethora of delicate, sensitive, or unique

portable goods. Small electronic components, jewelry, foods, expensive and precious articles, and any other item that requires a safe, stable, and portable environment in which to be shipped and stored may find an application with the present invention. Other advantages of the present invention will be apparent from the following description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

- [00018]** FIG. 1 is a plan view of an embodiment of a slide card blank;
- [00019]** FIG. 2 is a plan view of an embodiment of a pre-formed tray;
- [00020]** FIG. 3 is a plan view of an alternative embodiment of a pre-formed tray;
- [00021]** FIG. 4 is a plan view of an embodiment of an outer sleeve blank;
- [00022]** FIG. 5 is an isometric view of a completely constructed embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[00023] As required, detailed embodiments of the present invention are disclosed herein. It will be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The figures are not necessarily to scale, and some features may be exaggerated or minimized to show details of particular components. In other instances, well-known materials or methods have not been described in detail in order to avoid obscuring the present invention. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but as a basis for the claims and for teaching one skilled in the art to variously employ the present invention.

[00024] Referring now to the drawings, wherein like numerals represent like features throughout, there are illustrated embodiments of the present invention. Turning first to FIG. 1 and FIG 2, there is shown an internal slide card **10** and slide card tray **12**. As shown, the slide card **10** is configured to connectedly receive the tray **12** at a tray receiving area **14** and the tray **12** is configured to receive and store an item, such as a drug delivery device.

[00025] Herein, the phrase "drug delivery devices" is used broadly to refer to all apparatus and parts thereof used in conjunction with transferring substances into or out of a body, such as but not limited to a human being. By way of example and not limitation, a drug delivery device comprises a substance in the form of, or contained within, pills, tablets, chewables, aerosols, inhalers, trans-dermal patches, suppositories, injectable devices, parts thereof, and the like. Injectable devices comprise a plunger, barrel, and needle used by a medical professional to treat a patient with a pharmaceutical drug, or the patient to treat him or herself. For purposes of teaching and not limitation, the illustrated tray embodiments are directed to drug delivery devices in the form of injectable devices, but those skilled in the art will immediately understand that the tray may be configured to hold any portable item.

[00026] As best shown in FIG. 1, the illustrated card **10** includes a base panel **16**, spine panel **18**, top panel **20** and tab **22**. The respective panels are defined by fold-lines **24a, b**. Depending upon the material used to construct the card, fold-lines are formed by scores, cuts, bends, perforations, live hinges, formed hinges, and the like. As described in detail below, tab **22** may function as part of a means for locking and/or as part of a means for stopping by cooperatively engaging with a first element to create a child-resistant feature or cooperatively engaging with a second element to create a spill-resistant feature.

[00027] With regard to choice of materials, the slide card **10** may comprise paper, paperboard, cardboard, plastic, or combinations thereof. Where the slide card **10** comprises paperboard, bleached sulphate, solid unbleached sulphate, or clay-coated newsback are well-known design choices. Typically the paperboard coating is a fluid blend of materials, such as coating clay, calcium carbonate, and/or titanium dioxide with starch or adhesive smoothly applied to the traveling surface. Successive densification and polishing finish the mineral-coated surface to a superior, graphic-print surface. When the card and/or tray is paper, fabrication techniques well known to those skilled in the art, including vacuum forming, are contemplated. When the card and/or tray is plastic, fabrication techniques well known to those skilled in the art, including thermo-forming, injection molding, and the like, are contemplated. Where the slide card **10** is plastic, the fold-lines **24a, b** may be live hinges, or, as explained below regarding the engaging feature of the tab **22**, fold-line **24b** may be a formed hinge with an upwardly or downwardly extending profile to create an internal spring tension that urges the tab **22** back toward a relatively relaxed or horizontal orientation when the tab **22** is first folded over toward base panel **16**.

[00028] FIG. 2 and FIG. 3 show two possible alternative embodiments of pre-formed trays **12, 26**. Here, both trays **12, 26** are constructed of plastic, in the manner well known by

those skilled in the art, and are configured to receive and hold various items of various shapes. Also, as understood by those skilled in the art, both the exterior and interior tray configurations are merely design choices. Here, for purposes of teaching and not limitation, the exterior of the illustrated trays **12**, **26** are configured to be affixed to and within the tray receiving area **14** (best shown in FIG. 1), while the interior of the illustrated trays **12**, **26** are configured to receive and store drug delivery devices. One drug delivery device illustrated is a vial **30** for holding a medicament in liquid form and another is a syringe **32** to be used in conjunction with the vial **30**.

[00029] The tray **26** is configured to receive and store items of substantially uniform shape and size, such as the illustrated syringe **32** comprising a plunger **34**, barrel **36**, finger guard **38**, and needle **40**. The tray **26** comprises a means for securing and holding the syringe **32**, such as the plunger-receiving recess **42**, barrel-receiving recess **44**, and needle-receiving recess **46**. The recesses **42**, **44**, **46** may be configured to lock in or otherwise secure the item by including a means for resisting removal such as fold-over locking flaps, indentions, straps, inserts, and the like (not shown). Accordingly, a means for holding and storing a drug delivery device includes a pre-formed tray that can be configured in a variety of ways.

[00030] Regarding the illustrated embodiments, in practice the tray **12**, **26** is pre-formed separately and then affixed to the card **10** at the tray receiving area **14**, the location being merely a design choice. An alternative embodiment that is not illustrated comprises a monolithically formed card/tray combination. There it is contemplated that the slide card **10** is an integral part of the tray **12**, **26**, the two components being formed as a single unit during fabrication.

[00031] The tray **12** is configured to receive and store items of substantially unique shapes and sizes, such as the vial **30** and syringe **32**. Thus, tray **12** comprises a means for securing and holding the vial **30**, such as the vial-receiving recess **48**, and a means for securing and holding the syringe **32** as described immediately above. The recess **48** may be configured to lock in or otherwise secure the item by including a means for resisting removal such as fold-over locking flaps, indentions, straps, inserts, and the like (not shown). As understood by one skilled in the art, the various recesses illustrated herein may be configured to receive and store any portable items of any shape or size.

[00032] Here the trays **12**, **26** are also configured to allow for easy access to the items. By way of illustration and not limitation, the devices are arranged so that the end user, who may have limited physical mobility such as arthritis, can retrieve one device without affecting another. As illustrated, orienting the widest portion of the syringe **32** -- in this

example, the finger guard **38** -- to take the most space to provide the greatest accessibility is a desirable feature of this embodiment. Such horizontal orienting also provides easy viewing of the devices so the user may easily distinguish between them. Further, such orienting provides ample area to receive graphics. For example, dosage regimen instructions including date, day, and time may be formed on the tray sections between or adjacent to the recesses. Alternatively, the items held on the tray may be as closely packed and aligned as desired.

[00033] Patient and healthcare provider information, such as dose compliance, warnings, and instructions in written form or digital form can be made easily visible or accessible to the user through the ample billboard space found on either side of the panels **16**, **20**, tab **22**, or the components described below.

[00034] Turning now to FIG. 4 and FIG. 5, there is shown an outer sleeve **100** for receiving an inner card **10** with tray **12**, **26**, and the related outer sleeve blank **102**. As best shown in FIG. 4, the illustrated blank **102** includes side panels **104**, **106**, **108**, spine panels **110**, end panels **116**, **118** and extension panel **120**. The panels **104**, **106**, **108** are defined by the respective adjacent fold-lines **124a**, **b** and the respective outer edges **126**.

[00035] Side panel **104** comprises release button **130**, defined by release button cut **132** and release button fold-line **134**. Side panel **108** comprises a first engaging tab cutout **140** defined by cut-line **142**, and a second engaging tab cutout **144** defined by cut-line **146**. Side panels **104** and **106** further comprise access cutouts **148**. As explained below, first engaging tab cutout **140** and engaging tab **22** together form an embodiment of a means for locking, while second engaging tab cutout **144** and engaging tab **22** together form an embodiment of a means for stopping.

[00036] With regard to assembly, the blank **102** is folded and connected using conventional techniques to create the outer sleeve **100**, best shown in FIG. 5 as a slip case defining a void **150**. One sequence of folding and connecting the blank **102** is as follows, with reference to the visible side of the illustrated blank **102** as the face and the opposite side as the back. Extension panel **120** is folded back along transverse fold-line **124b**. Side panel **108** is then folded along longitudinal fold-lines **124a** under the side panels **106**, **104** and positioned under panel **104** so that the face of panel **108** may be affixed to the back of panel **104**. In this embodiment, panel **108** is affixed to panel **104** so that the first engaging tab cutout **140** is immediately under the release button **130**. In other words, in the illustrated embodiment the release button **130** is unobstructed by any solid surface of panel **108**. End panels **116**, **118** are folded inwardly so that the face of one end panel may be affixed to the back of the other.

[00037] Generally speaking, items are placed within inner tray **12, 26** and then the combined card **10** and tray **12, 26** is inserted into the void **150** of outer sleeve **100**. In the example of drug delivery devices holding unit doses, the Illustrated Unit Dose Packaging System (UDPS) secures these devices until they are retrieved for use. In practice, items are placed within the inner tray **12, 26** and then the various panels and tabs are folded before the combined card **10** and tray **12, 26** is inserted into the outer sleeve **100**. For purposes of teaching and not limitation, the following folding sequence is described. Top panel **20** is folded so as to cover the tray **12, 26** and orient the spine panel **18** adjacent to a side of the tray. Tab **22** is folded inwardly so that the face of tab **22** is proximate to the face of base panel **16**. With the card **10** folded as described, the combined card **10** and tray **12, 26** is inserted into the void **150** of outer sleeve **100** through the open end, starting with the edge formed by fold-line **24b** and with the tab **22** receivingly aligned with release button **130**, as illustrated in FIG. 5. The card **10** with inner tray **12, 26** is then fully inserted into the outer sleeve **100**, to a fully closed position.

[00038] With continued reference to FIG. 5, and as understood by those skilled in the art, spring tension created by the inwardly folded tab **22** causes the tab edge **154** to contact the interior side of panel **108**. Two particular points of contact along the interior side will be noted. From the fully closed position, the engagement of tab edge **154** with the internal edge **156** of cutout **140** at the locking position **A** provides a child-resistant feature. From a fully opened position, the engagement of the tab edge **154** with the interior of the folded extension panel **120** at the stopping position **B** provides a spill-resistant feature. The cutout **144** may be shaped to efficiently engage tab edge **154**. As illustrated, cutout **144** provides a semi-circular concave profile when panel **120** is folded, which engages well with the semi-circular convex profile of tab edge **154**. As understood by those skilled in the art, these engaging profile shapes are merely a design choice and not a limitation of the present invention. It will be understood that an embodiment of the UDPS may be constructed without either or both of the child-resistant or spill-resistant features.

[00039] In the illustrated embodiment the locking feature includes the release button **130**, cutout **140**, and cooperatively engaging tab **22**. The spring tension created by the folded tab **22** causes the tab edge **154** to engage the internal edge **156** of cutout **140**. With the tab **22** and internal edge **156** engaged, the inner tray **12, 26** is locked within the outer sleeve **100** and cannot be accessed. This means for locking creates a child-resistant feature. As illustrated, internal edge **156** has a semi-circular convex profile that engages well with the semi-circular convex profile of tab edge **154**. To unlock the child-resistant feature of this embodiment and

thereby access the tray 12, 26, the user depresses the release button 130, which in turn depresses the tab 22 to disengage the tab edge 154 from the internal edge 156.

[00040] After releasing the optional child-resistant feature the inner card 10 may be extracted from the outer sleeve 100 to a fully open position. In the illustrated embodiments, a fully open position occurs when tab 22 engages the interior of folded extension panel 120 at stopping position B. As will be understood by those skilled in the art, the spring tension created by the folded tab 22 causes the tab 22 to engage the folded interior of the extension panel 120. Once engaged, the card 10 cannot be further removed from the outer sleeve 100 but may be re-inserted to a fully closed position if desired. In this manner, tab 22 acts as a spill-resistant feature to prevent inner card 10 from being pulled completely out of sleeve 100.

[00041] It will be understood that a means for locking and a means for stopping are contemplated in various embodiments. For example, in the illustrated embodiment the extension panel 120 is not attached to side panel 108, but is allowed to extend downwardly into the void 150 to catch and engage the folded tab 22 as the card 10 is removed from the sleeve 100, thereby forming a means for stopping. In an alternative embodiment the extension panel 120 is folded inwardly and the respective backs of the panels 120, 108 are attached so that the extension panel edge 152 abuts tab edge 154, thereby forming a means for stopping. In the illustrated embodiment the first cutout 140 and the engaging tab 22 have a similar profile, which facilitates engagement of the respective edges 154, 156 and forms a means for locking. In alternative embodiments any edge or protrusion within the void 150 configured from panels, tabs, cutouts, ribs, offsets, catches, apertures, abutments, edges, and like elements, that engage the tab 22 or tab edge 154, forms an alternative means for locking or an alternative means for stopping. In yet another embodiment, tab 22 or edge 154 is connected to the tray 12, 26 to create a means for locking and a means for stopping.

[00042] The user may open and close the UDPS by withdrawing and replacing the inner tray 12, 26 within the outer sleeve 100 as often as desired. Regarding the illustrated embodiments, from the fully closed position the user grasps the card 10 at the top panel 20 and bottom panel 16, adjacent to the spine panel 18, from the access cutouts 148 provided in side panels 104, 106. The user then depresses the release button 130 in order to disengage the means for locking. Continuing to depress the button 130 while grasping and pulling laterally the card/tray will withdraw the tray 12, 26 from the sleeve 100. From the fully open position the user may fold back the optional top panel 20 to access an item held in the tray 12, 26. After accessing the desired item, the user folds the top panel 20 back over the tray 12, 26 and reinserts the card 10 within the sleeve 100 for future use.

[00043] An alternative embodiment (not shown) designed to be disposed of together with spent drug delivery devices, may be placed within a labeled plastic bag provided with the USPS thereby giving notice of its contents. By way of illustration and not limitation, additional means for protecting and sealing an embodiment that holds spent drug delivery devices until they can be disposed of together, include sealable bags, a self-sealing outer sleeve, a sealable outer sleeve large enough to receive the sleeve 100. Similarly, taping the inner tray within the sleeve with a labeled tape giving notice of the contents is a means for protecting and securing.

[00044] It is contemplated that the present invention is not limited to the pharmaceutical-related goods illustrated, but is applicable to a plethora of delicate, sensitive, or unique portable goods. By way of example and not limitation, small electronic components, jewelry, foods, expensive and precious articles, and any other item that requires a safe, stable, and portable environment in which to be shipped and stored may find an application with the present invention. Further, it will be understood that variations, modifications, and enhancements can be made to the disclosed apparatus and methods without departing from the scope of the present invention as defined in the following claims.